IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL NO. 13-CV-4507(CCC)

IN RE: DEPOMED PATENT LITIGATION

TRANSCRIPT OF
PROCEEDINGS
(P.M. Session)
(Public)

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Newark, New Jersey
March 14, 2016

B E F O R E:

THE HONORABLE CLAIRE C. CECCHI,
United States District Judge

Pursuant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

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Official Court Reporter

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W I T N E S S E S

T H O M A S C H R I S T O P H, sworn and testifies as follows:
CROSS EXAMINATION BY MR. ALY:
THE COURT: We are going to continue with the cross. And I will remind the witness that he remains under oath. Thank you.
Q. Good afternoon, Dr. Christoph.
A. Good afternoon.
Q. I would like also to start with timeline demonstrative slide 13 that you had presented.
This is the timeline you discussed on direct examination. Is that right?
A. Yes.
Q. And in that timeline you said that as compared to the tests and trials that you discussed during direct, everything that was on here that you discussed and nothing is missing. Is that right?
A. Yes.
Q. And if we can walk through some of those and I get to my questions here first the Bennett report in November 1994, that related to mononeuropathic pain, correct?
A. That's correct.
Q. And mono and polyneuropathic are two different kinds of pain. Is that right?
A. Yes.
Q. We have the Chung report here in December 2000 that

also related to mononeuropathic only. Is that right?

A. That's correct.

Q. And then December 18, 2002 you did the STZ experiments and that you said related to polyneuropathic pain. Is that right?

A. That's correct.

Q. And then in between December 18, 2002 and March 12, 2007, you didn't rush to the patent office in that time. Is that fair to say?

A. I don't recall any interaction with the patent office.

Q. Well, you had submitted a patent application in March 2007, correct?

A. Yes.

Q. And in between 2002 you did the STZ experiments. And in fact you waited about three years to do the vincristine test that you talked about?

A. It took quite some time to develop the vincristine model. As I said, this was done by, it was developed by Lillian Maymor (ph) and she came in early 2002. So we started to think about getting access to polyneuropathic pain models and somewhere in the range of maybe in the range of the Chung report.

We were thinking how could be get access to these models. And then we got the opportunity to bring in Lillian Maymor work to do the post work and she brought us or she had

the experience and the know how. And she developed during her post doc time a vincristine model. And she did quite some work on this vincristine model comparing it with a number of different other polyneuropathic pain models.

And in the end turned out that the vincristine would be the suitable one, robust enough one to make a, test a pharmacological test on it.

Q. So, your testimony is you took sometime to develop even the test to do the vincristine report.

Is that what you are saying?

A. We invested a lot of effort in developing the model until we got to the time when the vincristine was available.

Q. And it took you over three years even to come up with that model. Is that correct?

A. I don't know exactly the times but one might look in the details of the vincristine report and what time this was done. And I remember that we also, Lillian Maymor she left I think in 2004 and this model was also transferred to a technician who took over then the testing.

Q. And then before 2005 when the results were in about vincristine which you said was a good model, there are no other tests that you discussed between July 2005 and the time you filed the patent in March 2007. Is that right?

A. I don't know whether we discussed anymore models as I don't recall.

Q. And sir, did you at Grunenthal at this time between 1999 and 2007, was Tapentadol the only drug you were working on or were you working on other projects as well?

A. We worked on a number of different projects.

Q. More than five projects at the same time?

A. I don't recall.

Q. Of course there would be days if not weeks where you wouldn't be working at Tapentadol in that window of time.

Is that right? Between 1999 and 2007?

A. Could you repeat the question?

Q. Sure. There would be days if not weeks of time where you were not actively working on Tapentadol between the time frame of November 1999 and March 2007. Is that correct?

A. Well, if you look at the pure working time in the lab, that's, I think, correct. I don't recall how much we discussed internally on these data and what did we, what the result of these discussions were which led to further experiments.

Q. And so as far as the timing, we've addressed that now. I want to talk about the bottom half of this particular slide where you talk about these changes, references 1, 2 and 3.

Do you see that?

A. Yes.

Q. Do you agree that Dr. Tzchentke is not an inventor on the '130 patent?

A. That's correct.

Q. And Dr. Tzchentke was at Grunenthal at the time that you were, correct?

A. Yes, he was.

Q. You are the co-author on a couple of these Tzchentke references, correct?

A. Yes.

Q. Did you tell Dr. Tzchentke, please do not publish the information about Tapentadol, we haven't filed for a patent yet?

A. I don't recall talking to Dr. Tzchentke about the patent invention. I recall that he was the person responsible for bringing all pharmacological data together. And he also got the responsibility to write papers on this.

Q. And that's my question. Not only did you not tell Dr. Tzchentke to not publish, as a matter of fact you gave him all of the information specifically to publish it, right?

A. Well, this was the way the whole department did it because we had lots of, if you look at these different Tzchentke references, there are not only data on neuropathic pain, there are data on visceral pain also from my labs. There are data on acute nociceptive pain, inflammatory pain. All of these data came together.

And Dr. Tzchentke had the responsibility to somehow to act as a window person and to collect all these data.

Q. And isn't it true sir that Dr. Tzchentke collected that information including from you. And you knew he was going to make publications with that information, correct?

A. Well, he received all the information, of all the labs. And he was, his responsibility or his task was to do some publication of this.

Q. And did you know that that was his task at the time, to do some publication?

A. Yes, I knew this.

Q. Now as far as the materials that was included that Dr. Tzchentke gathered, he also gathered information from people that were not named as inventors on the '130 patent, right?

A. Yes, these were all these different data which were generated in the labs of my colleagues like Robert Kugle and Bob Shena (ph), like Thomas Tzchentke himself. This was all different data from the whole department.

Q. In all of the tests that you described, and I am talking about all of them that are appearing on demonstrative 13, not one of them was a human administrative trial, correct?

A. Well, since these were all pre Kugle data and Thomas Tzchentke who was also a colleague in the pharmacology, all of these pre-communicative data generated in rats and mice.

Q. Now Dr. Tzchentke's deposition was taken in this case. Do you know him to be someone who tells a falsehood or tells lies about what work people did on the articles he published?

A. Well, I know him as a responsible and truthful colleague. I don't know what he, what he witnessed. I have no idea.

Q. And so as far as you're here today if Dr. Tzchentke said something different than what you said about the materials in the articles, right now you don't have any reason to disagree with anything he said. Is that right?

A. Well, I wouldn't see what this could be. Of course it depends on the subject which he was talking about. But, this I cannot judge.

Q. Okay. Let's change then to a third topic with you and that is the declaration that you discussed with Mr. Schuler. And that is at PTX 1600 tab H production number GRTNUC 4045.

To make sure what we are looking at Dr. Christoph there was a point in time when the patent office said that we think that the invention you are submitting might be invalid, might be obvious.

Do you recognize that?

A. Well, if I remember correctly, there was some discussion on this including statements of these Buschmann reference and the Walken (ph) reference.

Q. And as part of the work that you did, you were asked to submit a declaration to the patent office during the time that the patent was being reviewed, right?

A. Well, I gave all my data to the patent office at that

time.

Q. And you were asked to put that in a declaration to the patent office, correct?

A. I don't recall.

Q. And in this declaration let's look at some information on production number, it will be Page 7 of the Document 44051.

This is some of the data appearing here Dr. Christoph that you submitted to the patent office, correct?

A. Yes.

Q. And if we can highlight the two graphs. Zoom in on those. And what we have in our comparison to the patent office is some tests with Tapentadol on top, correct?

A. That's correct.

Q. And morphine on the bottom, correct?

A. Yes, that's true.

Q. The reason you chose morphine is because it's an opioid, right?

A. The reason why we choose morphine was because it's the standard opiate. It's the gold standard for treatment of severe chronic pain conditions. And it's in the same ballpark as Tapentadol.

Q. Now, you knew, though, sir, at this time when you are submitting the declaration, that Grunenthal had Tramadol available, correct?

A. Yes.

Q. Tramadol was commercially available in fact, correct?
A. Sure.
Q. And you didn't submit any comparison of Tapentadol to Tramadol to the patent office, right?
A. But I think there is some comparison to Tramadol in the invention text in the patent.
Q. I'm asking about the data in the declaration.
Did you submit any comparison of data between Tapentadol and Tramadol, sir?
A. No. I mean in this model, as I said, this was a model which we newly developed, the C T analgesia model. And I don't think we tested Tramadol in this model because it wasn't considered to be the appropriate comparator.
It was morphine which we wanted to compare with since morphine has similar potency in acute nociception and morphine shows very different from Tramadol, shows similar abuse liability matters, abuse liabilities than compared with Tramadol.
So, to our understanding morphine was the correct comparator in this study.
Q. At the time you submitted the declaration, Dr. Christoph, you knew that Tramadol had two mechanisms of action, an opioid mechanism and a non opioid, correct?
A. Yes. We knew that Tramadol had an opiate agonistic activity. We knew that it had a norepinephrine reuptake of 55

HT reuptake and all of these need to be, as I said before, all of these needs to be activated and present and all are located on different entities of the molecule. So, it's a very complex mixture.

Q. And, sir, you also agreed on the cross-examination that Mr. Schuler did, that you in fact you yourself had published on Tramadol having the dual action opioid and non opioid before you signed this declaration, right?

A. This was a publication on Tramadol versus morphine in polyneuropathic pain. This is not --

Q. I think you answered my question.

A. -- the matter of this field.

Q. And on this particular model here in your declaration you said that morphine had, was not on -- sorry, let me start over. You said that morphine was a better comparison than Tramadol because Tramadol has different enantiomers that are in the mix?

A. No, this was a Tramadol statement.

Q. Because you know, sir, that morphine is a mixture of enantiomers also, right?

A. Morphine?

Q. Morphine.

A. The activity of morphine is solely, it's a MU receptor agonist.

Q. Do you know if morphine is a combination of enantiomers

or not, sir?

A. I don't think so.

Q. Morphine has five stereo centers doesn't it on the compound?

A. Well, I'm not a chemist.

Q. So you don't know how many enantiomers there are for morphine?

A. I couldn't draw you the chemical structure of morphine, sir.

Q. Do you understand then that Morphine has an active metabolite or activity metabolites. It's not morphine itself but the metabolites that are responsible for the opioid activity. Did you know that?

A. I know that morphine itself shows a strong opioid receptor agonistic activity.

Q. When given to man, it's the morphine M6 glucuronide, M6G for short? That's the most active MU opioid component and that's a metabolite, correct?

A. It's not so easy. It's also complex because M6G, to my recollection, is a strong MU opioid agonist which is, by the way, the same mechanism as the mother compound morphine, as morphine itself. And it gets, it gets metabolized so it will disappear by time.

So you have when giving morphine and it's metabolized to M6G, you will find only the MU opioid receptor activity

present in the treated subject. And that's different from Tramadol because there if you give Tramadol alone and give it to a subject which is not able to metabolize Tramadol, the subject will not receive any MU opioid receptor activity.

Q. Let me see if you can answer my question which is whether or not M6G is a metabolite of morphine or not?

A. M6G yes is a metabolite of morphine.

Q. Now, did you know that Tapentadol development at Grunenthal was part of what they called a Tramadol successor project? Did you know that?

A. Well, what, I don't know, at what time you think of?

Q. At the time you are submitting this declaration in 2011 did you know that at Grunenthal Tapentadol was part of the Tramadol successor project?

A. I knew that we wanted to generate a new analgesic which could overcome some of the problems which Tramadol was facing.

Q. Did you know that the name of the project at Grunenthal was Tramadol successor project?

A. I don't recall this.

Q. As far as the data that you submitted at anytime did you compare to the patent office Tapentadol and Tramadol? Not just this declaration, but at anytime?

A. Not that I remember.

Q. And the Harati article that you discussed with counsel that's an article you also didn't share with the patent office,

correct?

A. Well, to my recollection the data, the research reports were shared with the patent office. And in the research reports these articles are cited so they should know that this was in the research reports.

Q. So you are saying that you agree that you did not give Harati to the patent office but the patent office should have known by reading the reports, looking at the citation and digging through all of these on their own? Is that what you're saying?

MR. SITZMAN: Objection, your Honor, mischaracterizes the testimony.

THE COURT: Rephrase that question.

Q. I want ask do you agree that you did not separately submit Harati to the patent office?

A. I don't recall this.

Q. And your testimony is that the patent office should have been aware of Harati because it's cited in one of the technical reports that you also believe you submitted to the patent office. Is that right?

A. I will say yes.

Q. Thank you. No further questions.

THE COURT: Thank you. All right. Let's turn to the plaintiffs for redirect.

I'm sorry, was there anything additional?

MR.FITZPATRICK: Nothing for Actavis your Honor.

THE COURT: Anything else from the defendants' side? No? Thank you.

REDIRECT EXAMINATION BY MR. SITZMAN:

Q. Let me just go over a few, a couple of things. And actually I want to address one thing that Mr. Aly just addressed.

Could I have exhibit DTX 1031, please. It's column 12, Table 3.

Doctor, can I have you look at, it's the '130 patent DTX 1031. Do you see that?

A. Yes.

Q. Now, do you see Table 3 here in column 12?

A. Yes, I do see this.

Q. Mr. Aly asked you a bunch of questions as to whether or not you had told the patent office or supplied the patent office with any information comparing Tapentadol to Tramadol?

A. Uh-huh.

Q. Do you recall those questions?

A. Yes I do recall.

Q. And I just want to look here at Table 3 compound 9 here in table 3. What's that?

A. This should be Tapentadol.

Q. And the one above it?

A. That's Tramadol.

Q. Tramadol. Okay. And over here by the way just since we're here, the 100 percent here is it showing a hundred percent efficacy?

A. Yes.

Q. And Tramadol is at 86 percent efficacy when Tapentadol is a hundred. Is that correct?

A. It's correct.

Q. And you submitted this data to --

MR. SCHULER: Your Honor, can we have some non leading questions on redirect? It's still direct. This is leading.

MR. SITZMAN: I'm allowed to respond to the cross-examination.

MR. SCHULER: I'm not saying it's beyond the scope. I'm asking for non leading questions.

THE COURT: You can try and rephrase the question.

Q. All right. Can you tell us about the efficacy of Tapentadol here as disclosed in Table 3?

A. Sure. That means the efficacy, that's what I mentioned also during our previous discussion, that there is full efficacy, a hundred percent efficacy of Tapentadol in this model of polyneuropathic pain. And that's different from Tramadol which show efficacy of 86 percent.

Q. And that's also different than morphine too?

A. It's different from morphine and it's also different from Gabapentin, yes.

Q. And this data, did you supply this data to the PTO?

A. Well, I mean it's in the patent.

Q. Can I have DTX 2010.

Do you remember on cross-examination Mr. Schuler asked you some questions about this article?

A. Yes.

Q. And this is the article you're the lead author on?

A. Correct.

Q. Okay. Now, Mr. Schuler asked you some questions here about this paragraph that starts with however. Do you see that?

A. Yes.

Q. Okay. Sorry. I don't think he asked you about this.

Could you read that sentence if you can into the record there?

A. Which one?

Q. The one that begins however?

A. However, the debate about choice of appropriate treatment for neuropathic pain continues. And Tramadol amongst others, among others, is seen as one useful compound in this indication.

Q. Okay. And the debate that is referred to here is that the controversy that you were discussing earlier?

A. Yes.

Q. And so as of this writing your paper here, you didn't believe the debate had been resolved, had you?

A. That's correct.

Q. Do you remember that Mr. Schuler asked you some questions about this article?

A. Yes.

Q. And this is DTX 2009. Could you read the yellow highlighted sentence here?

A. As is generally the case with neuropathic pain, the treatment of PHN which is postherpetic neuralgia is presently unsatisfactory. Only tricyclic antidepressants have established efficacy in controlled clinical trials.

However, many PHN patients obtain no pain relief with these drugs and only occasionally is complete pain relief achieved.

Q. And then the last sentence on this page?

A. At the present time, there is serious controversy on the issue of whether opioid analgesics are of benefit in painful conditions such as PHN associated with damage to the central or peripheral nervous system.

For example, in patients with a wide variety of neuropathic pains, controlled intravenous opioid infusions failed to produce analgesia.

Q. Is that discussion consistent with your knowledge at

the time about the treatment of polyneuropathic pain and in particular PHN?

A. Absolutely. And I mean again if you -- it's again stating intravenous administration which means a high load of opioid which still fails.

Q. And actually that's what you testified to when you were responding to Mr. Schuler's questions. Is that correct?

A. Yes.

Q. Mr. Schuler also showed you this document which was really large. Luckily he didn't read it. The induction of pain. Do you remember that?

A. Yes, I do.

Q. Okay. Do you remember he showed you a table of definitions?

A. Yes.

Q. By the way, that's DTX 2012. Do you remember he asked you a little bit, he asked you about the pain definition here?

A. Yes.

Q. Okay. Let me bring your attention down to Number 8 analgesia. What does it say there?

A. Analgesia anti- nociception, a reduction in spontaneous pain or the pain elicited by a noxious stimulus.

Q. Is the anti-nociception, is that an understanding that you had at the time in terms of what analgesia meant at that

time?

A. At which time are you talking about?

Q. At the time of this article which is 1998.

A. 1998, yes. I mean this was, mainly analgesia was mainly in these days referring to established analgesics at that time, which were for chronic and severe pain, was the opiates.

Q. You didn't understand that the analgesias at this time were anti-neuropathic, right? They were synonymous with antinociception?

A. Yes.

Q. Let's turn quickly to the Buschmann patent DTX 120. Let me have column 23. There's a table there.

Now, Mr. Schuler asked you some questions about the Buschmann patent and what it disclosed.

Do you recall that?

A. Yes.

Q. And it disclosed or used the word "pain". Do you recall other than this writhing inhibition data, was there anything else in the Buschmann patent showing any efficacy?

A. Not to my knowledge.

Q. And the writhing inhibition, what kind of test is that?

A. That's a kind of acute nociceptive pain elicited by chemical stimulation.

Q. And was there any other indication in this patent,

based on your review of it, to suggest that the pain referred to here in this patent referred to anything other than antinociception?

A. No.

Q. Let me also pull up DTX 1030 and let's start on Page 15. Can you bring up the last paragraph on this page? Can you recall this is the report, the cross tolerance and tolerance report for Tapentadol. Do you remember that?

A. Yes

Q. Do you remember Mr. Schuler asking you about this paragraph about the old dogma?

A. Yes.

Q. Can we turn to Page 16, something that he didn't show you. And can you pick up mid-sentence mid-paragraph with these data. Can you read that sentence that begins with these?

A. These data are far from drawing a complete picture of the clinical situation, but at least they are leading in the same direction as the data of this report.

Q. And is that consistent with your recollection of where things stood when this report was written?

A. Yes.

MR. SITZMAN: I have no further questions your Honor.

THE COURT: Thank you.

MR. SCHULER: Just real briefly.

RECROSS EXAMINATION BY MR. SCHULER:

Q. Can you read the last two sentences of that paragraph?

A. If you show it to me, yes. Drugs with more than a single mechanism of action might be favorable to drugs acting respectively only at one target. This concept is also seen in the classical W.H.O. leader for the treatment of chronic pain conditions with drug combinations.

Q. It says W.H.O. leader. That's a typo?

A. That's a typo. Its means letter. That's referring to the W.H.O. recommendation for the treatment of I think mainly cancer associated.

Q. And that's multi-modal analgesia, correct?

A. Yes.

Q. What you're saying here is that tapping into with more than one mechanism of action consistent with the W.H.O. Letter, might be better for treating these, excuse me, chronic pain situations, correct?

A. This is comparing the, this is linking the finding to the effect, that's the W.H.O. letter, that the chronic severe cancer pain also recommends kind of a multi-modal pain treatment.

MR. SCHULER: That's it.

THE COURT: Thank you. Anything else?

MR. ALY: Yes, your Honor.

THE COURT: Okay.

RECROSS EXAMINATION BY MR. ALY:

Q. It's that new table we talked about, DTX 1031 at column 12 at eight I think on the PDF. Table 3.

Now I just want to make sure we understand the comparison, Dr. Christoph. Because I think Mr. Sitzman points out these numbers, 86 percent and a hundred percent.

Do you remember that?

A. Yes.

Q. The dose that as given for Tapentadol was 31.6 milligrams per kilogram, right?

A. Yes.

Q. The dose for Tramadol was two thirds of that, 21.5 milligrams per kilogram, correct?

A. Yes.

Q. And in fact surprisingly on the mechanical hyperalgesia the results were about the same between Tramadol and Tapentadol, right?

A. A little bit better for Tapentadol, yes.

Q. When you look at overall range, this range over here, they are overlapping, correct?

A. That's correct.

MR. ALY: Nothing further.

THE COURT: Thank you. Anything else?

MR. SITZMAN: No, thank you, your Honor.

THE COURT: Okay. Thank you. We have concluded with this witness. Thank you, doctor, very much for appearing today. You are excused at this point. Thank you. Your testimony has concluded. Thank you so much.

Are we ready with the next witness?

MR. SITZMAN: Yes, we are your Honor. Plaintiffs would like to call Dr. Michelle Brown to the stage or to the witness stand.

M I C H E L L E B R O W N, sworn and testifies as follows:

MR. ALY: Your Honor, we did discuss an objection to the demonstrative. I don't know if your Honor would prefer to do it beforehand or during.

THE COURT: I don't believe I received anything yet so why don't I get a set and we can see what we're talking about.

MR. SITZMAN: Yes please distribute those.

THE COURT: Before we get to that, are there any objections to the exhibits themselves or just this one demonstrative?

MR. ALY: From us, not for the exhibits.

THE COURT: Anyone ?

MR. CAPUANO: No objection.

MR. CONNOLLY: No objection.

THE COURT: Mr. Aly, what is the objection and which one is it?

MR. ALY: I have the larger version. I don't know if your Honor we're looking at the same slide 22.

MR. SITZMAN: Can you pull up slide 22 so we can see it on the big screen ?

MR. ALY: Or slide 23. So your Honor Dr. Brown's testimony is going to talk about the labels. All right. And as far as the labels are concerned we don't have a problem. What we do have a problem with is Dr. Brown addressing Alkem's intent, the company's intent, somehow reading the mind of the corporation saying Alkem had a specific intent to do X.

There's one rule of evidence about which there is much debate in the legal community is that an expert cannot testify about somebody else's intent or state of mind and we're not even --

THE COURT: I don't know what she is going to say. But, if what if she were to refer to factors and she would to say well, based upon my reading that establishes intent, would she be able to do so?

MR. ALY: No, your Honor.

THE COURT: As opposed to your actual mental intent. If she looked at certain indicia and pointed to certain indicia, would she be able to do that?

MR. ALY: No, your Honor, that is the ultimate question of intent. Talking about the label or what people

will do with the label or not do is fair game. But saying specific intention to induce infringement is not fair game.

THE COURT: Counsel.

MR. SITZMAN: I've never heard that objection ever before in my life, induced infringement requires intent. Infringement experts are allowed to speak to and address every single element. This expert did address this element in her report.

The defendant Alkem decided not to respond to it. Defendant Alkem then also had the opportunity to depose this expert on those issues.

The report was issued in June of last year. They've had fair warning of this issue. She has based her opinion on facts. She is entitled, as an expert, to render a decision on the ultimate, or opinion on the ultimate issue and that ultimate issue, as you know, includes intent. All right.

So it sounds like there was a long history. She disclosed it. There was certainly a deposition of this particular witness. Why would it be something that would be objected to at this point, given the opportunity for and full and fair disclosure on this? It doesn't appear to be surprise. And she is an expert. Shouldn't she be entitled to opine on these issues?

MR. ALY: No, your Honor, because that, what Mr. Sitzman is talking about is discovery obligations and having

the exchange and notice about the scope of the opinion. That's a Rule 26 issue, a discovery issue. We are not talking about Rules of Evidence.

And we believe, there are several cases, I have a sheet of cases that I can read into the record that says an expert cannot testify as to state of mind.

THE COURT: Although was that particular line of thought in her expert report presented through her deposition objected to at the time? I mean it certainly wasn't raised before me.

MR. SITZMAN: Correct, your Honor.

MR. ALY: This is the time to do it. This is the evidence where it's being presented. It wasn't being presented as evidence before. We wouldn't have, for example, a legal expert saying in response to Dr. Brown's report, no, you can't have expert testimony on intent.

We believe this is the first opportunity to raise that type of an objection as evidence as opposed to a discovery issue.

MR. SITZMAN: Your Honor, there's no rule of evidence that I'm aware of. I still haven't heard him cite a rule of evidence on this issue. My suspicion, based on his argument, is that he's reading from a bunch cases where an expert has testified about the emotional state of being of some other person.

As she disclosed in her expert report, her conclusion on specific intent is based on her review of the ANDA, the letter, the actions and all of the things that Alkem has done to infringe this patent. And she is going to testify shortly. The Court will take that evidence.

If Mr. Aly wants to move to strike and he thinks he's got authority for that, he should file a motion and do that. But at this point in time I believe there is no rule of evidence that would preclude her from testifying.

MR. ALY: Your Honor, the rules are 701 and 702. A person can only offer expert testimony about the area in which any person can be an expert.

THE COURT: But wouldn't she be competent as an expert to go back in the record and look at specific things that were either done or not done and draw a conclusion based upon her experience?

And the question was an apt one by Mr. Sitzman in terms of the cases, do you have them precisely in this context or are they dealing with someone's sort of emotional thoughts at a specific point in time? I mean there is a long or a lengthy continuum in terms of these issues.

MR. ALY: No, they are, in fact I was familiar with one of these. I happened to be in one of them in the district of Delaware in 2004 and that's another New Jersey case over in the circuit. This is pretty common.

THE COURT: What's the case? What's the cite? Do you have a copy of it for the Court?

MR. ALY: I do not have a copy. I can share with you this excerpt we have. I would be happy to do that or if you want, your Honor, as Mr. Sitzman said, to brief it later, we are happy to do that too.

THE COURT: I think she sounds like she is competent to enter into this testimony, to provide this testimony. If she bases it on something that you think is not appropriate, certainly you can raise it as an issue to strike. But, again, if she is going to be testifying, we heard a preview of what she is going to be testifying as to.

And if she's going to be testifying as to certain activity, I would think that that would be appropriate in this circumstance. But, perhaps maybe the best mode is just to see how it unfolds. And if you still have an objection, you can raise it at that time. How does that sound?

MR. ALY: We will do so, your Honor.

THE COURT: Is that good for everyone?

MR. SITZMAN: Yes, your Honor.

THE COURT: All right. Let's proceed. Also actually before we go forward, what is the citation Counsel is referencing?

MR. ALY: The one I read?

THE COURT: Yes.

MR. ALY: 345 F Supp 2d 431 at 443.

THE COURT: 431 at 443. And what's the name of the case?

MR. ALY: Oxford Gene Technology versus Mergen.

THE COURT: Is there an additional case?

MR. ALY: There are several, your Honor.

THE COURT: Would you like to list them all off or would you like to give copies to the Court? You can just list them off now just so we will have them.

MR. ALY: Bracco Diagnostic, 627 F Supp 2nd 384 at 440. Astra Zeneca versus tap, 444 F Supp 2nd 278 at 293. In re: Rosuvastatin calcium patent litigation 2009 Westlaw 4800702.

THE COURT: What is what the last one in re: Rosuvastin, I'm sorry R-o-s-u-v-a-s-t-a-t-i-n and Astra Zeneca versus Watson labs.

THE COURT: I'm sorry for the last one what was the actual cite for it.

MR. ALY: The in re: Rosuvastin. The cite is 2009, W.L. 4800702 at eight.

THE COURT: At eight okay.

MR. ALY: And Astra Zeneca versus Watson labs, 2012 W. L. 6043266 at two.

THE COURT: Okay.

MR. ALY: Thank you.

THE COURT: Thank you. Let's proceed.

MR. SITZMAN: Thank you, your Honor.

M I C H E L L E B R O W N, sworn and testifies as follows:

DIRECT EXAMINATION BY MR. SITZMAN:

Q. Good afternoon.

A. Good afternoon.

Q. Could you please state your name for the record?

A. Dr. Michelle Brown.

Q. And Dr. Brown could you tell us a little bit about your educational background?

A. Yes, I went to medical school at the university of Florida. I did an internship in internal medicine at Mount Sinai medical center in Miami. Following that I returned to the university of Florida and completed a residency in anesthesiology. This was followed by a special fellowship in pain management at the university of Florida.

I stayed at the University of Pennsylvania in 1997 as an assistant professor of anesthesiology and pain management. Following that, I retained a courtesy clinical associate professor appointment at the university of Florida until 2011. However, simultaneously, I was in private practice from 1997 until now.

Q. And let's take a look at the next two slides. Does this reflect your current employment, sorry, this does reflect that employment history that some of which you just touched on

, correct?

A. Yes, it does.

Q. Okay. And in the slide before that, could you tell us what's reflected here on this slide?

A. Yes. I currently am employed by Unifour anesthesiology associates in hickory, North Carolina. And I work as a staff anesthesiologist and pain management physician at about 9 to 10 locations that we staff. I'm also a member of our executive committee of our practice. We manage the entire practice of 20 physicians and 70 additional employees.

And part of my role on this committee is to supervise all of our medical directors of our clinics, pain clinics. You may see that it says Associate medical director at some of our pain clinics, we assign that name to me at the pain clinics where I staff so that the patients and the staff that work there know that they can come to me specifically with problems at those locations.

But overall my duty on the executive committee is to oversee the medical directors. I work to deal with compliance issues, quality measures, managing the staff. I develop policies and procedures. And of course I field complaints too.

Q. How long have you worked at Unifour?

A. Since 2001.

Q. Okay. And generally, if you were to put a label on it,

what kind of doctor do you describe yourself as?

A. I'm an anesthesiologist and I have a sub specialty certification in pain management.

Q. How much time do you spend on a weekly basis seeing patients?

A. I spend about 30 hours per week face to face with patients seeing them in the pain clinic. Overall my week may vary putting in anywhere from 40 to 80 hours depending on my call duties. But I also work in the operating room anesthetizing patients for surgical procedures. But on average about two-thirds of my time is spent seeing patients at the pain clinic.

Q. And how many pain patients would you estimate that you see on a monthly basis?

A. About 500.

Q. And how many active pain patients do you currently have under your care?

A. I would estimate around 3,000.

Q. And can you describe for us, you know the typical pain patient that you see in the pain clinic?

A. Usually a patient is referred to me because they have pain and their physician is unable to manage that pain be it their primary care physician or surgeon or some other type of specialist.

The most common painful syndrome that we will see

involves spine pain, it may involve low back pain or neck pain. Following that we may see other pain conditions like diabetice neuropathy or fibromyalgia. We may also see joint discomfort as well but there's many things that we see

Q. Were you retained to provide expert testimony in this case?

A. Yes I was.

Q. And by whom?

A. Depomed.

Q. At this phase in the case in terms of where the case is today and trial, what were you asked to do?

A. I was asked to assess whether the defendants in this case have infringed the method of treatment claims of the '130 patent if allowed to market and sell their generic versions of Nucynta ER.

Q. And more specifically were you asked to look at induced infringement for the defendants?

A. I was.

Q. And were you also asked to look at contributory infringement?

A. Yes, I was.

Q. And did you make those assessments?

A. I did.

Q. And at a high level what is, if you can give us summary of those opinions of infringement of the '130 patent?

A. Alkem will infringe claims 1,2 3 of the '130 patent if they are allowed to market their generic drug. Both Roxane and Actavis will infringe claims 1 and 2 of the '130 patent if they are allowed to market their generic drug.

Q. And generally speaking what do you base these opinions on?

A. On my clinical experience as a pain management physician but also on many of the documents I have reviewed in this case.

Q. And among those things you reviewed the defendant's proposed labels for their generic versions of the Nucynta ER drug?

A. Yes.

Q. And you reviewed other portions of their ANDA applications as well?

A. Yes.

MR. SITZMAN: Your Honor, I would like to offer at this time Dr. Brown as an expert in pain management and treatment, including the management of patients with nociceptive and neuropathic pain.

THE COURT: Any objection?

MR. CAPUANO: No objection.

MR. ALY: No.

THE COURT: She is, in fact, deemed as an expert in these areas.

MR. SITZMAN: Before I continue forward, I think I know that but if I get close, will you let me know.

MR. CAPUANO: Yes.

Q. All right. Let's take a step back for a minute and talk a little bit more generally about pain. What is your definition of pain?

A. Pain is an unpleasant and emotional sensory experience that is associated with actual or potential tissue damage or it can be explained in terms of such damage.

Q. And would you agree then that pain is a symptom? Is that how you describe that?

A. Yes, I would.

Q. And a symptom would be distinct from a cause of a pain, correct?

A. Yes, it is.

Q. What types of pain do you find relevant in this case and in rendering your opinions?

A. Nociceptive versus neuropathic pain. Acute versus chronic pain. Intensity of pain described as mild, moderate, or severe.

Q. Let's briefly chat about nociceptive pain. What is nociceptive pain?

A. Nociceptive pain is pain involving specialized nerve endings that are called nociceptors. When nociceptors are activated, this is in response to actual potential tissue

damage. A patient will describe this sort of pain as a throbbing or an aching pain much like a toothache or hitting your thumb with a hammer is another example.

Typically this is a very distinct pain when a patient is describing it to us.

Q. What about neuropathic pain and can you give us some examples?

A. Neuropathic pain is pain that results from damage to or dysfunction of the nervous system. A patient will describe this very differently than nociceptive pain. Typically they will describe it as a burning sensation an electrical or shocking sensation, a pins and needles sensation.

Examples of this could include diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia. A lot of people consider that to be an neuropathic pain.

Q. And can certain pain conditions be a combination of both nociceptive and neuropathic?

A. Yes, and we usually call these a mixed pain syndrome.

Q. And do you have an example of a mixed pain syndrome that we can think about?

A. Most common example is chronic low back pain.

Q. And that has elements of both nociceptive and neuropathic?

A. Yes.

Q. What is acute pain?

A. Acute pain is pain that generally will last anywhere from 3 to 6 months. It's expected to be self limited or that it will heal overtime.

Q. Can you contrast that with chronic pain. How do you define chronic pain?

A. Chronic pain is pain that generally will last further than six months and is not expected to heal.

Q. Between acute pain and chronic pain, which one falls within the label of Nucynta ER?

A. Chronic pain.

Q. And why?

A. Because this discusses pain that requires around the clock coverage but for an extended period of time or for a long term and that would indicate chronic pain.

Q. Focusing on chronic pain then and just chronic pain for a minute, can chronic pain also be nociceptive?

A. Yes, it can.

Q. And I assume then chronic pain could also be neuropathic?

A. Yes it can and probably most often is.

Q. Most often is neuropathic?

A. Neuropathic, yes.

Q. What is that, your assessment there, what is that based on, that it's most often neuropathic?

A. I base that on my clinical experience but also when you

assess nerves, nerves don't regenerate very well. They don't grow back like if you were to cut your hand with a knife you expect that's going to heal. But nerves don't really regenerate very well.

And the classic example of this is Christopher Reeve's spinal cord injury. You don't expect something that is a damage to the nervous system like that to recover very well. That's a clear example of why that turns chronic.

Another reason is and I think some of the other experts, medical experts in this case have said this is neuropathic pain is very difficult to treat and you can't seem to get it under control and typically will turn into a chronic pain because of that.

Q. Doctor, what is severe pain?

A. Severe pain really refers to the intensity of pain. And there's many ways that we refer to the intensity of pain. This is just one of them. And we use a grade like mild, moderate or severe with severe being the worst.

Q. And as I asked with the other symptoms we talked about, can severe pain be nociceptive in nature?

A. Yes.

Q. And can it be neuropathic?

A. Yes.

Q. All right. Let's take a look at the '130 patent. Can I have the -- there we go.

You're aware that the plaintiffs have asserted claims 1, 2, 3 and 6 of the '130 patent against Alkem, correct?

A. Yes.

Q. And that the plaintiffs have also asserted claims 1 and 2 against Actavis and Roxane?

A. Yes.

Q. And I think you said this earlier, you understand that claims 1, 2, 3 and 6 are all method of treatment claims?

A. Yes.

Q. Now, could you just describe in your own words as you are looking at claim one, does that cover -- how do you read claim one?

A. It's a method of treating polyneuropathy pain using Tapentadol.

Q. Okay and is claim two different from claim one in your perspective?

A. Only in the sense now that Tapentadol is being described as a salt.

Q. And is claim, sorry, so what type of, just looking at 1 and 2 for a second, what type of pain do you believe claims 1 and 2 cover?

A. Polyneuropathic pain.

Q. Is claim three different from claims 1 and 2?

A. This claim discusses only diabetic polyneuropathic pain which is a type of polyneuropathic pain.

Q. And claim six, does that also cover diabetic polyneuropathic pain?

A. Yes, I think diabetic polyneuropathy is just worded slightly differently here but again it's still a type of polyneuropathic pain.

Q. Now, doctor, in prescribing a drug to a patient do you read the package insert or label for the drug?

A. I do. In fact the FDA wants us to.

Q. Have you ever been instructed or were you ever instructed in medical school that you should not read the package insert for a drug before prescribing a drug to a patient?

A. No I was never taught that.

Q. Do you think it's reasonable for a physician to ignore the package insert or label?

A. No, I don't think that's reasonable.

Q. And how many physicians again do you work with in your group that you oversee?

A. We have twenty physicians.

Q. And based on your work with them and your oversight, do your colleagues read the package inserts and labels of the pain medications that they prescribe?

A. They do. In fact, at some of my locations I work with more than one physician at the same location in a day and I can tell you that we may be standing at the nurse's station looking

at a package insert figuring out how to prescribe it for somebody. And this is a teaching opportunity for the both of us.

If there's two of us, for example, and as a supervisor if a physician with whom I work prescribes a medicine in an unsafe manner, I will hear about it. And if that happens it's certainly brought to my attention.

Q. Now, aside from the package insert and the label, do you also read literature about approved drugs and prescribing them to patients?

A. I do.

Q. And when you have a patient in your office, do you rely on the label or do you rely on the literature when you prescribe a particular drug?

A. Practically speaking I relied on the label. This is information that's been scientifically vetted by the FDA. If I have a patient who is sitting in my waiting room and Mrs. Jones is in there waiting for me to write a prescription, it is very impractical for me to go pull the literature on a particular drug and see what it says.

And I rely upon the label in those situations to prescribe a medication, I have a license to prescribe effectively the proper doses and make sure that I'm not going to bring harm to that patient.

Q. Let's take a look at the Nucynta ER label starting with

its original version.

Can I have PTX 1499 ?

And do you recognize this document, doctor?

A. Yes. This is the original label for Nucynta ER when it was FDA approved in 2011.

Q. And Ross can you blow up the indications and usage section on the left column there ?

What was Nucynta ER originally approved for in 2011?

A. It was indicated for the management of moderate to severe chronic pain in adults when a continuous, around the clock opioid analgesic is needed for an extended period of time.

Q. Can polyneuropathic pain be moderate to severe chronic pain as described here in this indication?

A. Yes, it can. I think the other experts in this case have also said the same thing.

Q. Let's take a look at a little deeper into this first label. Page 273457. And if you can blow up the first part of the clinical study section there.

And you see disclosed there the chronic low back pain study. Do you see that?

A. Yes.

Q. Okay. And you understand that this was one of the studies that was submitted in the approval process for Nucynta ER?

A. Yes it was.

Q. Can you describe just on a high level what the results show in terms of Nucynta ER? You may need the rest of that label. But in terms of the Nucynta ER in the performance here in this chronic low back pain study.

A. Yes, it showed that patients who on average had severe low back pain were given either Nucynta ER or placebo and showed improved pain relief with Nucynta ER compared to placebo.

Q. I think we talked about this at the outset but it is your belief that chronic low back pain can be polyneuropathic? Is that what you said?

A. Yes, and it often is.

Q. In your experience, in your practice, do you see patients with chronic low back pain who have a polyneuropathic cause?

A. Yes. Chronic low back pain is probably one of the most common painful syndromes and I see and it frequently does have polyneuropathic pain associated with it, particularly as it gets chronic and severe.

Q. Now, Dr. Weinberger and Actavis have argued that chronic low back pain consists of neuropathic components. Do you agree with that?

A. No, I don't.

Q. And what do you rely on for that opinion?

A. My clinical experience but also on some of the literature.

Q. Let's take a look at one of them that was used the other day. Can I have PTX 872. This is the Morlion or Morlion, I'm going to get my French down soon, Morlion reference.

Do you recognize that?

A. Yes I do.

Q. You've read this article and this reference before I take it?

A. Yes.

Q. Let's look at Page 870. Down there in the last paragraph, thanks, Ross.

Now, Actavis and Dr. Weinberger argue that this portion of this reference supports their position that chronic low back pain rarely has a neuropathic pain component.

Do you agree with that?

A. No I don't.

Q. And can you explain why?

A. This is very difficult to read. But, looking at the numbers that are presented here, such as the first sentence that overall 80 to 90 percent of patients with low back pain are thought to experience pain arising from a nociceptive mechanical cause, while that statement may be true, this is encompassing acute and chronic low back pain. There is no

mention that this is specifically chronic low back pain. Go ahead.

Q. And only chronic low back pain would fall within the Nucynta, correct, Nucynta label, correct?

A. Yes.

Q. Is there a mention of low back pain in this section that Actavis is relying on?

A. Although it's difficult to read, the sentence that begins with however towards the bottom does references that.

Q. And what does that say?

A. It says However, note that this percentage is higher in the presence of a neuropathic pain component when chronic low back pain is considered.

Q. All right. Can we also turn, since we are in this article, can we turn to Page 869? I believe it's at the bottom of this first column, the part of chronic LBP and we may need the paragraph on the top of the second column.

Does this section of Morlion also discuss chronic low back pain?

A. Yes. This is a little more specific to chronic low back pain here.

Q. And here it references, it looks like at the bottom of the first pull out thus recent studies have demonstrated that approximately 20 to 50 percent of patients with chronic low back pain have a greater than 90 percent likelihood of a

neuropathic pain component.

Is that consistent with your practice and your understanding?

A. Yes and I think even further the further statement that an additional 28 percent of patients with a neuropathic pain component is suspected. And then the next sentence is also I think quite relevant, the presence of neuropathic pain component is associated with more severe pain symptoms.

Q. Excellent. All right. Despite all of this that we just looked at, are all forms of chronic low back pain neuropathic?

A. No.

Q. Okay. So they can be, they can have nociceptive components?

A. They can be nociceptive, mixed or neuropathic.

Q. So, given this, do you have an opinion as to whether chronic low back pain would fall within indication one of the Nucynta ER label for moderate to severe chronic low back pain?

A. Yes, chronic low back pain would fall into that indication.

Q. Okay. And do you, what do you base that opinion on?

A. I base that on literature like this, my clinical experience and also on the label.

Q. In fact, there was a chronic low back pain that was submitted with the label?

A. Yes.

Q. Are there other studies that were submitted with the original Nucynta ER label?

A. Yes.

Q. Can we go back to that? It's Nucynta 458. This is the other study that you are referring to?

A. Yes.

Q. What study is this?

A. This is the study looking at the benefits of Nucynta ER in patients who had painful diabetic peripheral neuropathy. And in fact this study at the time was pivotal because with any type of drug that had MU opioid receptor activity, we had never seen a pure neuropathic pain model used in support of FDA approved in any way. It was the first time. And this was quite remarkable.

And I remember thinking about this that this was something that I have never seen before.

Q. And these results are reported in the label here. Is that correct?

A. Yes.

Q. And I guess this goes without saying but I just want to confirm, DPN is a type of polyneuropathic pain?

A. Yes, and the studies showed that patients showed improved pain relief with Nucynta ER compared with placebo.

Q. Do you have an opinion as to whether DPN falls within

the first indication of the label for moderate to severe chronic pain?

A. Yes, it falls within the label and also it appears that the FDA thought that too.

Q. Let's go to PTX 1383. I want to show you, move to the current label of Nucynta ER, and if you could blow up the indications and usage section again.

Do you recognize this document?

A. Yes, this is the current Nucynta ER label.

Q. Okay. And focusing on these indications and usages, what is Nucynta ER currently indicated for?

A. The first indication is pain severe enough to require daily around the clock long term opioid treatment and for which alternative treatment options are inadequate.

And the second indication, the neuropathic pain associated with diabetic peripheral neuropathy otherwise known as DPN in adults severe enough to require daily around the clock long term opioid treatment and for which alternative treatment options are inadequate.

Q. Can pain severe enough to require daily around the clock long term opioid treatment be polyneuropathic?

A. Yes, and it often is.

Q. Now are you aware of why there was a wording change from the original label we just looked at to this one in terms of indication one?

A. No, I'm not.

Q. Other than the wording difference, do you view them clinically different in any way, shape or form?

A. No, I don't.

Q. When you look just at indication one for a second, is there any particular cause of the pain symptom that is specified in indication one?

A. No, simply for pain.

Q. So that's the symptom that we talked about earlier?

A. Correct.

Q. Indication two, is that a particular cause associated with the symptoms?

A. Yes, that's specific to diabetic peripheral neuropathy.

Q. And does diabetic peripheral neuropathy fall within indication one?

A. Yes, it does.

Q. Do other causes fit within indication one?

A. Yes.

Q. And does polyneuropathic pain describe many of those causes?

A. Yes.

Q. All right. Turning to second 14, one of the current labels which is Page 9. Thanks Ross.

These are the clinical study section. It looks like a second study has been added. Do you see that?

A. Yes.
Q. And what is that additional study?
A. An additional DPN study was added to the current label.
Q. How does this new DPN study affect your opinions in this case.
A. It does not.
Q. And why not?
A. Because it doesn't change clinically how I may prescribe the drug. There was already a DPN study in the original label.
Q. So if we can go on to the next demonstrative I just want to confirm your understanding.
Then that indication one, I'm sorry, indication one was supported with the first two studies we see here?
A. Yes.
Q. And then indication two was supported with the second DPN study, correct?
A. Yes.
Q. All right. And if we can have the next to confirm your understanding then actually go back one I think. There we go.
Indication one, in your opinion, that indication one covers claims 1, 2, 3 and 6 ?
A. Yes.
Q. And indication two, what does that cover?

A. Claims 3 and 6.

Q. Okay. So I know you're not a lawyer but I would like to go through the different types of infringement you were asked to address in this case and that we talked on very early on in this examination.

Can we have, there we go.

Do you understand that to find induced infringement there must be direct infringement, knowledge that the actions would cause infringement and specific intent to induce infringement?

A. Yes.

Q. And to find contributory infringement there must be those same first two elements, direct infringement and knowledge that the actions would cause infringement plus, no substantial noninfringing uses and that the component must be a material part of the invention?

A. Yes.

Q. Did you agree with those elements in this case?

A. Yes, I did.

Q. Let's take Alkem first.

MR. ALY: Your Honor, this may be a good time as we enter into the information presented by defendant, to have the courtroom sealed.

MR. SITZMAN: That's fine. I was going to wait until we got to Actavis but that's fine.

THE COURT: Would you like to do that now?

MR. ALY: Sure.

THE COURT: We are going to clear the courtroom so counsel obviously will remain and the clients will remain. Everyone else must wait outside.

MR. KANDARA: John Kandara, a California attorney, member of the public.

It appears that during Dr. Weinberger's testimony yesterday there was at least some of that testimony that should have been open to the public and was not. We have heard some of that discussion today.

THE COURT: I am not certain what you refer to but if someone knows what this gentleman is speaking of, maybe you can enlighten me. I'm getting nods no.

MR. KANDARA: I will tell you right now. It appears there was some discussion by Dr. Weinberger about some papers, a paper that he was using to cite to. Let's see, a paper that he cited to support his opinion.

All I'm asking, if I can find, the reference, it was PTX 870 pages 869 and 870, he discussed, the paper discussed whether chronic low back pain did or did not have a polyneuropathic component.

What I'm asking is that to the extent that there is any discussion today that would not relate directly to the labels and what the labels say, the parties would police

themselves a little bit better than they did yesterday and allow the public back in.

THE COURT: We are narrowly tailoring this and we have the entirety of the proceedings open to the public with the exception of a very small portion of the testimony.

MR. KANDARA: I understand that.

THE COURT: That has been highlighted by counsel and they determine whether it's time that we are going to be discussing something that is subject to sealing at that point.

And we have many documents in the case, obviously that have been sealed previously, not exactly on this date, but previously sealed. And if we are talking about any areas that go into that, obviously the courtroom needs to be sealed.

If you believe there has been some portion, a small portion that may have been included in the sealing that shouldn't be included in the sealing, I'm not certain exactly as to what that is. I know you mentioned something today. I don't know if counsel know anything about that or why it's being brought up. But obviously we're trying to narrowly tailor that.

MR. KANDARA: I understand.

THE COURT: We've asked members of the public be excused. As we attend to, that there may be testimony that is subject to sealing not for any other reason.

Let me hear from counsel on this if you have any

other information that can bear upon this.

MR. CAPUANO: Your Honor, in a 10 or 15-minute exchange, there are going to be a handful of questions, maybe more, that aren't related to confidential information. I don't think it's practical to open and close the door for five questions and then send people out again and have them ushered in and out.

It's just we are trying to do the best we can to be as narrowly tailored as you to protect our client's information.

THE COURT: Counsel.

MR. SITZMAN: I just want to comply with the concerns that everybody has. It seems to me, though one thing that dawns on me, I guess we'll have to go back to the transcript anyway, we could always, when we have the transcript in front of us --

THE COURT: We could unseal a portion of it.

MR. SITZMAN: Unseal the portions, but at this point there's --

THE COURT: There's nothing being done here to prevent the public from hearing matters aside from those that are actually sealed.

MR. KANDARA: I understand, your Honor.

THE COURT: As the Court needs to be very mindful of protecting the record because certainly that is my job here.

MR. KANDARA: I was only --

THE COURT: So, as counsel for Actavis has mentioned, if he does ask a question that perhaps is not something that pertains to something to be sealed because he is following up with before and after with questions that need to be protected, obviously that has to be covered here. We could have at left members of the public go in and out after every question but we are trying to work it out in as best a way we can work it on.

MR. KANDARA: I am not asking for every other question, your Honor. I am asking to the extent that counsel is aware that there is going to be a block of questions that is not related to confidential information, they inform the Court of that and have the courtroom reopened until such time as there is another block of confidential information.

THE COURT: I totally understand.

MR. KANDARA: That's all I'm asking.

THE COURT: I totally understand. I believe they have been working in a very cooperative method and way to get that done and to insure that is adhered to but our goal is all the same here. We have one goal to protect that which needs to be protected. And beyond that certainly we are interested in providing this as being an open forum for the public.

But I do need to make sure that whatever counsel has told me needs to be protected, that certainly we operate on

that principle. And if there is anything that has gone by which looks like it has been covered through a section of testimony that has been sealed, we can take a look at that at a future time.

As I indicated, our goals are to provide the litigants here, the parties with the protection that they deserve regarding their particular documents and testimony that need to be protected, and balance that against what the public needs. And we have been doing this in a way that insures that the public can hear you know everything that can be given to the public. So we are not trying to do anything but that.

So, let me take down the pages of the testimony you are looking at and certainly counsel can look at that and see if there's any issue. You mentioned it was at the beginning but we don't have that before us right now. So tell me what it is and counsel will take a look at it and get back to me.

MR. KANDARA: Apparently on some discussion yesterday during Dr. Weinberger's testimony of the Morlion article PTX 872 and whether it supported his opinion that chronic low back pain rarely has a polyneuropathic component. Such discussion clearly does not involve one label or another or the language that's included in that label and thus should not be considered confidential.

THE COURT: Okay. We don't have a transcript

right now but when we get that transcript, we will certainly take a look at it and direct counsel to take a look at it. And if there is any reason that it needs to remain sealed, you will let me know that.

If there's any reason that it can be open to the public, you will let me know. How does that sound?

MR. SITZMAN: We will do.

MR. CAPUANO: We will.

THE COURT: We will all endeavor to work together on this issue so there are no further complications. Thank you. At this point we are however to seal the courtroom because I have been informed that the following material is privileged, confidential, highly confidential, needs to be retained.

So let me go through and I will do the same. I will follow the same procedure that I have been following. Let's see all the folks from the plaintiffs. We have Depomed. Let's see you folks. Grunenthal. Actavis. Roxane. Alkem. All right.

Anyone else? We have someone in the corner. You are here with one of the teams. With Roxane. All right. Let's go. Let's seal the courtroom.

(Whereupon the hearing is sealed).

(Whereupon the following takes place in open court)

MS. SHARKEY: We are going to pass out corrected Mogil exhibits.

THE COURT: These are corrected? These look like demonstratives.

MS. SHARKEY: These are demonstratives corrected in hard copy after the discussion on Friday.

MR. CONNOLLY: You may recall Mr. Schuler and Mr. Sitzman had a discussion about a couple of slides, reached an accommodation, and I think that we promised to get you replacement slides. Because I think at some point there were either handwritings or blackouts or whatever. It's just it reflects the agreement among counsel.

THE COURT: I got it. Okay. That makes sense. Thank you.

MR. CONNOLLY: I know that there's no reporter here to report on that important development.

THE COURT: We did just unseal the room so.

MR. CONNOLLY: Right.

THE COURT: It is unsealed. Everyone is free to listen. In any event, do we have anything else that we need to discuss today before we break?

MR. CONNOLLY: Not from Roxane. Your Honor.

THE COURT: Anything?

MR. ALY: No, your Honor

MR.FITZPATRICK: No.

MR. SITZMAN: Nothing, your Honor.

THE COURT: Excellent. We will be adjourned for the evening. I look forward to the continuation of the cross-examination tomorrow morning. And I think that's it.

And again who did we say was going to be on the witness stand for the remainder of the day thereafter?

MR. ALY: Two witnesses, Steed and Wolf.

THE COURT: And they are?

MR. ALY: Steed is a polymorph expert that Alkem is calling.

MR. CONNOLLY: And Dr. Wolf, your Honor, is a stereochemistry expert. He is going to testify about enablement and written subscription. And then keeping in the theme of the trial, he is also a German who speaks accented English.

THE COURT: We are getting very used to that. We will be in good shape.

Anything else? We are going to conclude. Thank you very much, everyone. Much appreciated for your time and effort today. Thank you.

(Whereupon the matter was concluded).